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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,015	03/30/2000	Thomas R. Winston	15225-00041	7690
7590 10/21/2003				
John S Beulick Armstrong Teasdale LLP One Metropolitan Square Suite 2600 St Louis, MO 63102-2740		EXAMINER SMITH, RUTH S		
		ART UNIT PAPER NUMBER		
		3737		
		DATE MAILED: 10/21/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 09/539,015	Applicant(s) WINSTON ET AL.	
	Examiner Ruth S Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to disclose that the guide wire distal end comprises at least one stationary fiber of the interferometric guidance system. It is unclear as to what the fiber is stationary with respect to. The fiber is part of the apparatus which is guided into the body so that it must inherently involve movement of the fiber and therefore cannot be stationary.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,7-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Tearney et al. Tearney et al disclose a method and apparatus for guiding a guide wire (34) through body tissue including an interferometric guidance system (4) and circuitry (18) for generating Doppler shift information. Tearney et al further disclose an illumination source (2), first and second optical fibers (22,32) wrapped around

piezoelectric transducers (90), a beam divider (6), a fixed reflector (12) and a detecting element (16). The apparatus of Tearney et al is capable of performing the function as set forth on lines 5-6 of claim 1. The guidewire distal end is considered to be stationary with respect to at least one axis of the endoscope in which it is positioned.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5,6,12,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tearney et al in view of Peterson et al. Tearney et al disclose a method and apparatus for guiding a guide wire (34) through body tissue including an interferometric guidance system (4) and circuitry (18) for generating Doppler shift information. Tearney et al further disclose an illumination source (2), first and second optical fibers (22,32) wrapped around piezoelectric transducers (90), a beam divider (6), a fixed reflector (12) and a detecting element (16). Tearney et al fails to disclose the use of a frequency to voltage converter. Peterson et al disclose an apparatus for performing Doppler blood

flow studies wherein processing circuitry (590) includes a frequency to voltage converter (col. 9, lines 18-20). It would have been obvious to one of ordinary skill in the art to have modified the apparatus of Tearney et al such that it includes a frequency to voltage converter to facilitate computerized processing of frequency signals as is well known in the art.

Claims 14, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izatt et al in view of Tearney et al. Izatt et al disclose performing Doppler shift analysis on signals generated by an interferometric system examining a sample including blood vessel to determine the velocity of blood. Izatt et al fails to disclose the specifics of the apparatus used to perform the method. Tearney et al disclose a method and apparatus for guiding a guide wire (34) through body tissue including an interferometric guidance system (4) and circuitry (18) for generating Doppler shift information. Tearney et al further disclose an illumination source (2), first and second optical fibers (22, 32) wrapped around piezoelectric transducers (90), a beam divider (6), a fixed reflector (12) and a detecting element (16). The guidewire distal end is considered to be stationary with respect to at least one axis of the endoscope in which it is positioned. It would have been obvious to one skilled in the art to have modified Izatt et al such that it includes the specific apparatus of Tearney for generating the Doppler shift information. The modification merely involves the substitution of one known type of interferometric system for another for obtaining information regarding the velocity of blood flow through a vessel.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izatt et al in view of Tearney et al as applied to claim 14 above, and further in view of Swanson et al. Swanson et al disclose a method for performing optical measurements including Doppler shift analysis and using either linear or sinusoidal changes in path length. It would have been obvious to one skilled in the art to have further modified Izatt et al to include the Doppler shift analysis as taught by Swanson et al. Such a

modification merely involves the substitution of one type of Doppler shift analysis of optical signals for another.

### ***Response to Arguments***

Applicant's arguments filed September 30, 2003 have been fully considered but they are not persuasive. It should be noted that claim 1 has not been amended to recite applicant's guide wire with an optical fiber forming its distal end as set forth on page 7 of applicant's response.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 3737

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read 'Ruth S. Smith', written in a cursive style.

Ruth S Smith  
Primary Examiner  
Art Unit 3737

RSS